

WHAT IS CLAIMED IS:

1                   1.       A sample collection device for collecting a biological sample from  
2 a mammary organ of a patient, comprising:

3                               a breast engaging member constructed of a non-porous material  
4 sized and dimensioned to receive at least a nipple portion of a breast of said patient and  
5 form a suction seal therewith;

6                               a solid phase sample collection medium in fluid connection with  
7 said breast engaging member for receiving a sample of expressed breast fluid; and

8                               vacuum pump means in gaseous connection with said breast  
9 engaging member for generating negative pressure through the breast engaging member  
10 to facilitate breast fluid expression, wherein the sample collection device is a hand-held  
11 breast pump incorporating said breast engaging member and vacuum pump means in a  
12 compact, structurally integrated breast fluid collection apparatus that can be manipulated  
13 and operated with one hand.

1                   2.       The sample collection device of claim 1, wherein said solid phase  
2 sample collection medium is selected from the group consisting of microscopic glass  
3 slides, capillary tubes, collection tubes, columns, micro-columns, wells, plates,  
4 membranes, filters, resins, inorganic matrices, beads, resins, particulate chromatographic  
5 media, plastic microparticles, latex particles, coated tubes, coated templates, coated  
6 beads, coated matrices, or a combination thereof.

1                   3.       The sample collection device of claim 1, wherein said hand-held  
2 breast pump comprises a modular device formed of a plurality of components that are  
3 joined or securable in fixed structural interconnection with one another and may be  
4 partially or completely disassembled to remove or uncouple the individual components as  
5 desired for efficient operation, cleaning, servicing and/or storage.

1                   4.       The sample collection device of claim 3, wherein said modular  
2 breast pump device includes a separate breast engaging member constructed of a rigid or  
3 semi-rigid, non-porous material sized and dimensioned to receive at least a nipple or  
4 areolar portion of a human subject's breast and form a suction seal therewith, wherein

5 said breast engaging member is detachable from one or more interconnecting components  
6 of the hand-held pump device for cleaning and sterilization or to allow for interchanging  
7 of different engaging members to accommodate breast anatomy differences among  
8 patients.

1                   5.       The sample collection device of claim 1, wherein said solid phase  
2 sample collection medium is supported by a support member removably mounted in fluid  
3 connection with said breast engaging member.

1                   6.       The sample collection device of claim 5, wherein said support  
2 member is provided as a removable cassette that can be inserted within said breast  
3 engaging member to be removably mounted in fluid connection therewith.

1                   7.       The sample collection device of claim 5, wherein said support  
2 member supports one or more pads or sheets of absorbent or adsorbent material.

1                   8.       The sample collection device of claim 1, wherein said solid phase  
2 sample collection medium comprises a nitrocellulose membrane.

1                   9.       The sample collection device of claim 8, wherein said  
2 nitrocellulose membrane has a pore size selected to effectively retain whole cells from  
3 expressed breast fluid on a surface of the membrane.

1                   10.      The sample collection device of claim 7, wherein the pad or sheet  
2 is a modified membrane or filter having perforations or slits that disrupt the planar surface  
3 of the membrane or filter to facilitate air passage therethrough and impart structural  
4 flexibility against mechanical perturbation.

1                   11.      The sample collection device of claim 5, wherein said support  
2 member incorporates one or more air channels that pass through a body of the support  
3 member for passage of vacuum pressure therethrough and/or to serve as channels for  
4 passage or breast fluid sample materials between the breast engaging member and a  
5 sample collection housing member of the hand-held breast pump.

12. The sample collection device of claim 1, further comprising a fluid-retaining recess, well or reservoir integrated or fluidly connected with the support member or a sample collection housing member of the hand-held pump device.

13. The sample collection device of claim 12, wherein the fluid-retaining recess, well or reservoir comprises an integral, defined compartment or enclosure within the sample collection housing for receipt of breast fluid and/or constituent samples thereof

14. The sample collection device of claim 12, wherein the fluid-retaining recess, well or reservoir comprises a removable fluid reservoir member of the sample collection housing.

15. The sample collection device of claim 14, wherein the removable reservoir member is a rigid sample collection tube or vial removably connected with an outer casing member of the housing that partially or completely encloses the tube or vial.

16. The sample collection device of claim 14, wherein the removable reservoir member is a rigid sample collection tube or vial removably, sealably connected with an outer casing member of the housing to form an airtight coupling therewith.

17. The sample collection device of claim 14, wherein the removable reservoir member is a cytology vial sealably connected with an outer casing member of the housing to form an airtight coupling therewith.

18. The sample collection device of claim 17, wherein the removable reservoir member and outer casing member of the housing are coupled to form an assembled sample collection housing, wherein the reservoir member is removably nested within the casing member to form a substantially airtight contact between an inner wall of the casing member wall and an outer wall, or a top or bottom end, of the reservoir member.

19. The sample collection device of claim 18, wherein an outer wall of the removable reservoir member features a circumferential ridge, fin or O-ring that

3 engages and makes a circumferential airtight seal against the inner wall of the casing  
4 member when the vial is nested within the casing member.

1 20. The sample collection device of claim 14, wherein the removable  
2 reservoir member is gaseously and fluidly connected with the breast engaging member to  
3 facilitate sample collection.

1 21. The sample collection device of claim 14, wherein vacuum  
2 pressure from the vacuum pump means is routed to the breast engaging member through  
3 the removable reservoir member of the housing.

1 22. The sample collection device of claim 21, wherein the removable  
2 reservoir member is modified to include one or more air ports that form a gaseous  
3 connection between a lumen of the reservoir and the vacuum pump means.

1 23. The sample collection device of claim 14, wherein the removable  
2 reservoir member functions as both a conduit for vacuum pressure transmission to the  
3 breast and a receptacle for fluid sample materials to directly collect expressed fluid or as a  
4 secondary collection medium to receive primarily collected sample materials washed or  
5 otherwise transferred from a primary solid phase sample collection medium.

1 24. The sample collection device of claim 14, wherein the removable  
2 reservoir member communicates for fluid and gaseous transmission directly with the  
3 breast engaging member or indirectly therewith by way of air channels in a support  
4 member optionally coupled with the breast engaging member.

1 25. The sample collection device of claim 14, wherein a primary solid  
2 phase sample collection medium fluidly connected with the breast engaging member is  
3 positioned to collect a primary sample of one or more breast fluid components which can  
4 thereafter be washed or otherwise transferred directly or indirectly into the removable  
5 reservoir member without removal or disassembly of the breast engaging member and  
6 reservoir member.

1 26. The sample collection device of claim 25, wherein the primary  
2 solid phase sample collection medium is a nitrocellulose membrane for retaining cells and  
3 other cytological materials on a surface of the membrane.

1                   27.     The sample collection device of claim 25, wherein the primary  
2 sample collection medium is supported in fluid connection with the breast engaging  
3 member by a support member, and wherein the support member includes one or more  
4 sample transfer channels for transfer of the primary sample from the primary collection  
5 medium, through the channels into the removable reservoir.

1                   28.     The sample collection device of claim 27, wherein the sample  
2 transfer channels extend through tubular basal columns or other fluid connection ports  
3 that extend from the support member toward, or into, a lumen of the fluid reservoir  
4 member.

1                   29.     The sample collection device of claim 14, wherein the removable  
2 reservoir member is a cytology vial having one or more air ports that communicate  
3 between an outer wall and inner lumen of the vial to form a gaseous connection between  
4 the lumen of the vial, the vacuum pump means, and the breast engaging member.

1                   30.     The sample collection device of claim 14, wherein the removable  
2 reservoir member further comprises closure means for closure of the reservoir after  
3 sample collection is completed to prevent sample contamination and spillage, whereby  
4 the removable reservoir serves a multi-purpose function for sample collection as a  
5 component of the breast pump device as well as for storage, transport and/or processing  
6 of the sample upon removal of the reservoir member from the device.

1                   31.     The sample collection device of claim 30, wherein the closure  
2 means comprises a cap adapted to sealably engage a top end of the removable reservoir  
3 member.

1                   32.     The sample collection device of claim 30, wherein the reservoir  
2 member is modified to include one or more air ports that form a gaseous connection  
3 between a lumen of the reservoir and the vacuum pump means when the reservoir  
4 member is engaged with the pump device, and wherein the closure means further  
5 comprises secondary closure means to sealably close the air port(s) after sample  
6 collection.

1           33.     The sample collection device of claim 32, wherein said secondary  
2 closure means comprise an adhesive seal or sticker sized and constructed to adhere to an  
3 outer wall of the reservoir member surrounding an air port opening.

1           34.     The sample collection device of claim 32, wherein said secondary  
2 closure means comprises a combined closure and labeling device which functions as a  
3 secondary closure mechanism to seal the air port(s) of the removable reservoir and as a  
4 labeling template to provide a writing surface for sample labeling.

1           35.     The sample collection device of claim 32, wherein said secondary  
2 closure means comprises a combined closure and labeling tab or sticker which may be  
3 directly applied to seal the air port after sample collection having a first, closure-forming  
4 surface for application over the air port to form a seal by juxtaposition or adhesive contact  
5 with an outer wall of the removable reservoir, and a second, labeling surface opposite the  
6 closure-forming surface made of a blank template material suitable for receiving a stable,  
7 ink or graphite imprint thereon.

1           36.     The sample collection device of claim 35, wherein said first,  
2 closure-forming surface bears an adhesive coating resistant to disruption by contact with  
3 aqueous solutions.

1           37.     The sample collection device of claim 32, wherein said secondary  
2 closure means comprises a combined closure and labeling tab or sticker which is pre-  
3 attached to the removable reservoir member in a first, open configuration and can be  
4 manually repositioned or otherwise manipulated after sample collection to a second,  
5 closed configuration to form a seal or closure against the air port(s).

1           38.     The sample collection device of claim 37, wherein said secondary  
2 closure means comprises an adhesive tab or strip folded in the open configuration to form  
3 an inner layer affixed to the reservoir proximate to the air port and an outer layer folded  
4 over the inner layer, said outer layer providing the first, closure-forming surface and the  
5 second, labeling surface, wherein the outer layer can be unfolded away from the inner  
6 layer and wrapped around the reservoir so that the closure-forming surface covers the air  
7 port to form a fluid-resistant closure and the labeling surface faces outward for  
8 recordation of sample data.

1                   39.     The sample collection device of claim 38, wherein the outer layer  
2 is optionally secured in a folded-back position against the inner layer by adhesive  
3 engagement of the labeling surface with the inner layer.

1                   40.     The sample collection device of claim 39, wherein said first,  
2 closure-forming surface bears an adhesive coating that is protected in the open  
3 configuration by folding of an end segment of the outer layer bearing the adhesive coating  
4 back, so that the closure forming surface provides a protective surface to shield the  
5 adhesive prior to closure, whereby the end segment can be lifted and pulled outward to  
6 unfold the end segment to separate the adhesive coating on the closure-forming surface  
7 from the protective surface and to release the outer layer from the inner layer for closing  
8 of the air port(s).

1                   41.     The sample collection device of claim 14, wherein the breast  
2 engaging member includes removable coupling means for removable coupling of the  
3 breast engaging member with a complementary coupling surface of the sample collection  
4 housing.

1                   42.     The sample collection device of claim 41, wherein the sample  
2 collection housing includes an outer casing member and a removable, fluid reservoir  
3 member, and wherein the engaging member can be directly coupled to the fluid reservoir  
4 member.

1                   43.     The sample collection device of claim 42, wherein the breast  
2 engaging member has coupling threads to engage complementary threads of an open end  
3 of the removable reservoir, said complementary threads of the reservoir adapted to  
4 interchangeably receive a cap that sealably engages the reservoir open end.

1                   44.     The sample collection device of claim 43, wherein the removable  
2 reservoir member is a modified cytology vial.

1                   45.     The sample collection device of claim 1, wherein the solid phase  
2 sample collection medium is adjustably mounted relative to the sample collection housing  
3 so that the solid phase collection medium can be controllably moved closer to, or farther  
4 away from, a base of the engaging member of the pump during use.

1                   46.     The sample collection device of claim 1, further comprising a  
2 reciprocating mechanism which adjustably moves the solid phase sample collection  
3 medium in closer, or more distant, proximity to the nipple when the hand-held breast  
4 pump is engaged therewith.

1                   47.     The sample collection device of claim 1, further comprising a  
2 compact vacuum pump housing which structurally and functionally integrates the vacuum  
3 pump with the sample collection housing.

1                   48.     The sample collection device of claim 47, wherein the vacuum  
2 pump housing and outer casing member of the sample collection housing are cast or  
3 molded as a single, integral component of the device.

1                   49.     The sample collection device of claim 1, further comprising a  
2 vacuum pump actuating mechanism connected to a vacuum pump housing of the device.

1                   50.     The sample collection device of claim 49, wherein the vacuum  
2 pump actuating mechanism comprises an actuating lever pivotally connected to the pump  
3 housing.

1                   51.     The sample collection device of claim 49, wherein the pump  
2 housing includes an integral handle opposing an actuating lever pivotally connected to a  
3 base portion of the handle.

1                   52.     The sample collection device of claim 1, wherein the vacuum  
2 pump means comprises a flexible diaphragm member and pump actuation means to draw  
3 the diaphragm member away from a primary vacuum chamber connected with, or  
4 integrated within, the sample collection housing.

1                   53.     The sample collection device of claim 52, further comprising a  
2 vacuum pump housing, wherein the primary vacuum chamber is integrally formed within  
3 the vacuum pump housing proximate the flexible diaphragm member and extends to a  
4 communicating port opening to the sample collection housing.

- 1                   54.     The sample collection device of claim 53, further comprising a  
2 removable fluid reservoir member of the housing modified to include one or more air ports  
3 that form a gaseous connection between a lumen of the reservoir and the communication port  
4 to gaseously connect the lumen of the reservoir to the primary vacuum chamber.

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